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QM31/0504

EXAMINER	
PREBILIC, P	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 05/04/98

Please find below a communication from the EXAMINER in charge of this application.

Commissioner of Patents

Office Action Summary

Application No.
08/737,492

Applicant(s)
Burmeister et al

Examiner
Paul Prebilio

Group Art Unit
3738



☒ Responsive to communication(s) filed on Feb 20, 1998

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire Three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-20 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-20 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 3738

The abstract of the disclosure is objected to because it fails to adequately describe the invention. The Examiner suggests adding the following sentences thereto in order to more fully describe the invention: ---These tissue supporting devices are generally cylindrical or tubular. They have at least one component with a tendency to self-expand the device and another component which is deformable, by an external force, to maintain further expansion.---. Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, lines 1-4, the relationship of the member, the device, and the first and second portions is not clearly set forth. For example, does the first portion make the member self-expanding? In order to overcome this objection, the Examiner suggest changing "device further" to ---member--- (line 2), deleting "and the member" (line 8), and replacing "deformed" with ---- further expanded---- (line 9).

In claim 11, line 11, and claim 20, line 9, the language "in comprising the stent" confuses the scope of the claim and is not understood since the relationship of the alloys has been set forth. For this reason, the Examiner suggest deleting this language.

Art Unit: 3738

In claim 11, line 2, the relationship of the “member” and “stent” with respect to the “device” is unclear and it appears that some of the subcomponents thereof are double included by the language of claim 11. In order to overcome this indefiniteness, the Examiner suggest inserting ---further--- after “shape” (on line 2) and deleting “a permanent . . . having a body of” (on lines 2-3).

In claim 11, lines 19-20 and claim 20, line 19, the terminology “without plastic deformation” appears to contradict the disclosure as set forth in the specification which states that deformation (i.e. plastic deformation in that it permanently bends the wire elements to a new and permanent shape) takes place when the graft is expanded from the initial deployed diameter to the fully deployed diameter; see page 2, lines 14-19. Since the deformation of the balloon is intended to be permanent, it follows that plastic not elastic deformation takes place. For this reason, the preclusion of plastic deformation in the claims contradicts the clear teaching of the specification. In order to overcome this rejection, the Examiner suggest deleting the objectionable language.

In claim 11, line 12-13 and claim 20, line 10-11, the language “upon transformation of the first portion from austenitic to martensitic at a temperature below the transition temperature” is confusing because it is unclear which transition temperature is being discussed and because this language contradicts the disclosure of the invention as set forth in the specification. Furthermore, the transition temperature is the temperature at which the austenite changes to martensite or vice versa. For this reason, to say that this transformation takes place below the transition temperature is contradictory to the meaning of “transition temperature”. In addition, the specification sets

Art Unit: 3738

forth that the first portion transition from martensitic to austenitic state is below body temperature so that the first portion is normally austenite and becomes self-expanding after this transition; see pages 7 and 8 of the specification and Figures 3, 4a, and 4b; therefore, this recited portion of the claim contradicts the specification disclosure and is confusing in view thereof.

In claim 11, line 19 and claim 20, line 19, the “whereby” clause is improper because it contains functions therein which are not inherently provided within the body of the claim. Therefore, the Examiner suggest changing “whereby” to ---wherein--- in order to overcome this objection.

In claim 15, line 1, “cable-like” is considered indefinite because of the modifier “like”; the Examiner suggest deleting this term in order to overcome this rejection.

In claims 12-19, the preamble is improper because it does not agree with what is set forth in the base claim 1. Furthermore, it is considered improper to claim a subportion of what is set forth in the independent claims. Therefore, the Examiner suggest changing the word “stent”, in claims 12-19, to ---device--- in order to overcome this objection.

In claims 16-19, it is unclear which alloy is being further modified because two alloys are set forth in claim 11 from which these claims depend. For this reason, the term “alloy”, as used in claims 16-19, lacks clear antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 3738

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 2, and 8-10 are rejected under 35 U.S.C. 102(e) as being anticipated by Andersen et al (US 5,366,504); see Figures 7-7d wherein the first portion as claimed is met by the self-expanding ends (42,44) of Andersen and the second portion as claimed is met by the self-expanding graft portion (80) of Andersen.

Possible Interference

Upon updating the search for the present application, the Examiner discovered a patent to Freitag (US 5,601,593) which appears to be quite relevant, conceptually, to the applicant's claimed invention. It sets forth two types of nitinol wires with two different transition temperatures such that the presently claimed invention could be viewed as obvious in view thereof. Therefore, the Applicant has two options with respect to the Freitag patent as follows:

(1) Amend the claims to clearly set forth that the claimed invention is patentably distinct therefrom. During the interview of April 17-21, 1998, the Examiner suggest some changes which would distinguish the claimed invention from that of Freitag, but the Applicant did not agree to such changes. The changes included the ones suggested above in connection with the Section 112 rejections and the following:

Art Unit: 3738

In claim 1, line 7, after "diameter", insert ---which is larger than the deployable diameter----.

In claim 1, line 10 and claim 20, line 21, after "enlarged", insert --self-sustained--.

However, upon further searching, the Examiner discovered the Andersen patent which has been applied under Section 102 and which was not considered in making the above proposed amendments. The Applicant would also have to overcome this rejection either by amendments or arguments.

(2) Copy the claims from the Freitag patent so as to provoke an interference therewith and show how there is support in the Applicant's disclosure to meet the claim language. At least the broadest independent claim (i.e. claim 1) must be copied either identically or substantially identically to how it is set forth in Freitag.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nicholas (US 5,478,349) is cited to show that the concept of partial self-expansion followed by further mechanical expansion has been known to the art; see column 5, lines 5-11.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilio whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

Serial Number: 08/737,492

Page 7

Art Unit: 3738

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu, can be reached on (703) 308-2672. The fax phone number for this Group is (703) 308-3590.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
Art Unit 3738